IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

LOU ANN RUNION, et al.

Plaintiffs,

v. CIVIL ACTION NO. 2:11-cv-00525

UNITED STATES OF AMERICA,

Defendant.

MEMORANDUM OPINION AND FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. INTRODUCTION AND PROCEDURAL HISTORY

Plaintiffs bring this medical malpractice action under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 2671-80. Plaintiffs' claims, which allege medical negligence under West Virginia's Medical Professional Liability Act ("MPLA"), W. Va. Code § 55-7B-1 *et seq.*, and loss of consortium, arise out of Plaintiff Lou Ann Runion's treatment by David M. Rainey, M.D. during and immediately following her eighth pregnancy. Mrs. Runion developed an ischemic bowel following the September 4, 2008 Cesarean delivery of her son, allegedly due to Dr. Rainey's failure to properly guard her against thrombosis. At all relevant times, Dr. Rainey was employed by Community Health Systems, Inc., d/b/a Access Health ("Access Health"), a federally-funded health care provider in Raleigh County, West Virginia.[1] Employees of Access Health are deemed to be federal employees under 42 U.S.C. § 233. Thus, this Court has jurisdiction and venue is proper. 28 U.S.C. § 1346(b)(1). Plaintiffs seek damages for medical

[1] Access Health was formerly doing business as Associates in Obstetrics and Gynecology, PLLC.

expenses, lost wages, non-economic damages, including loss of consortium, and other compensatory damages.

After exhausting their administrative remedies as required by 28 U.S.C. § 2401(b), Plaintiffs filed their Complaint on August 2, 2011. As required by 28 U.S.C. § 2402, this matter was tried to the Court without a jury on January 8, 9, and 10, 2013. In accordance with Rule 52(a)(1) of the Federal Rules of Civil Procedure, the Court now makes its findings of fact and conclusions of law. All findings of fact are made by a preponderance of the evidence.

II. PRELIMINARY FINDINGS OF FACT AS TO MEDICAL HISTORY

1. On January 31, 2008, Plaintiff Lou Ann Runion presented for prenatal care at Access Health. She was estimated to be 10 to 12 weeks pregnant with an approximate delivery date of September 12, 2008. She was seen on that day by Dr. Rainey, and he remained her primary obstetrician throughout her pregnancy.

2. This was Mrs. Runion's eighth pregnancy. Three of her prior pregnancies had ended in miscarriage, one in ectopic pregnancy, and one in stillbirth due to placental abruption. She also had one prior Cesarean section after failed labor, followed by a successful vaginal birth after Cesarean section. Mrs. Runion was a long-time cigarette smoker and obese. As part of her prenatal care, Dr. Rainey prescribed vitamins B6 and B12, folate, and baby aspirin. Dr. Rainey also ordered a thrombophilia workup on May 12, 2008. The laboratory results came back normal with the exception of an MTHFR gene mutation. The results identified two copies of the A1298C mutation, though results for the C677T mutation were negative. (Joint Ex. 2, ECF 65-1.) Mrs. Runion's functional Protein S activity was 50L.

3. On September 4, 2008, Mrs. Runion was admitted to Raleigh General Hospital at 38 weeks and 6 days gestation for concerns associated with her low amniotic fluid, or

oligohydrammious. On that date, she underwent an uncomplicated repeat low transverse Cesarean section followed by a bilateral tubal ligation. Spinal anesthesia was administered in conjunction with the surgery. Mrs. Runion's infant son was healthy upon delivery with APGAR scores of 8 and 9. Dr. Rainey performed the surgery and rendered the following postoperative diagnosis: "Term pregnancy, oligohydrammious. Previous Cesarean section. Breech presentation. History of intrauterine fetal demise. Thrombophilia with positive homozygous MTHFR mutation and undesired future fertility." (Joint Ex. 2, ECF 65-1 at 9.) Mrs. Runion was not ordered to wear sequential compression devices ("SCDs") and was not treated with anti-coagulant medications either before or after her Cesarean section.

4. Mrs. Runion appeared to be recovering well after her surgery on September 5 and 6, 2008, though her nurses noted some abdominal bruising on September 6. Her condition deteriorated on September 7. Her abdominal bruising increased, and she reported nausea and vomiting. Her hematocrit was 18.9%, down from 36.3% at her admission. She received a blood transfusion. On September 8, Mrs. Runion's condition worsened still. She experienced shortness of breath. Her symptoms being consistent with the development of a severe infection, her providers planned to treat her with antibiotics overnight and, if no improvement, consider re-exploratory surgery of her abdomen. In an attempt to rule out abnormal clotting as the cause of Mrs. Runion's distress, Dr. Rainey ordered a CT scan of her chest on September 8, 2008. This scan revealed no trace of pulmonary emboli. (Def. Ex. 8, ECF 62-8.)

5. Dr. Rainey consulted with several other physicians about Mrs. Runion's condition on September 8 and 9, 2008. Among them was Dr. Ramzi Nimer Haddadin, who, after examining Mrs. Runion and reviewing her medical history, rendered the following impressions:

> Acute hypoxemia and shortness of breath with mild wheezing and anemia with sinus tachycardia and abdominal distention, pulmonary embolus ruled out,

> pneumonia not obvious, sepsis is a possibility, myocardial infarction is less likely. Bronchospasm is also a possibility. . . . [A]t this time I will hold off anticoagulation due to the anemia and abdominal wall bleed and gastrointestinal possible abdominal bleed and abdominal wall bleeding.

(Pl. Ex. 13, ECF 61-15 at 4.)

6. On September 9, 2008, Mrs. Runion's abdominal distension and bruising had increased. A CT scan of Mrs. Runion's abdomen was performed and revealed "[f]indings consistent with nonspecific adynamic ileus." (Def. Ex. 10, ECF 62-10.) The scan showed fluid in the abdomen consistent with hemoperitoneum. Dr. Rainey requested a surgical consultation from Dr. Scott M. Killmer. Dr. Killmer's consultation report dated September 10, 2008 stated:

> History of Present Illness: This is a 33-year-old female approximately six days out from a C-section. Since then, she's had difficulty with abdominal pain, abdominal peri-incisional bruising, and breathing. She has had slightly worsening abdominal discomfort and distention. She has had rising leukocytosis as high as 30,000, at this time 23,000. She has been tachycardic in the 120's and continues to be approximately 120. She is afebrile. She [was] ruled out for pulmonary embolism. She does have some mild chronic lung disease. She has asthma and smokes. No significant other past medical history. Bowel movements have been only small and only with enemas. She has passe[d] no spontaneous gas or bowel movement.
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> Physical Examination: On exam, she appears slightly sick. Head and Neck: Within normal limits. Lungs: With mild rhonchi. Abdomen: Moderately distended and moderately tender, particularly in the left lower quadrant and right lower quadrant. She has a large ecchymosis of the lower abdomen around the incision. There is no fluctuance and no drainage. Incision is intact. There were absent bowel sounds. Extremities: Without clubbing, cyanosis, or edema.
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> Assessment: Abdominal pain with peritoneal signs, tachycardia, and leukocytosis.

(Pl. Ex. 15, ECF 61-17.) Based on this examination, Dr. Killmer recommended exploratory surgery of Ms. Runion's abdomen.

7. Mrs. Runion was taken to surgery on September 10, 2008, six days after her Cesarean section. Dr. Killmer performed the surgery with Michael Belcher, a physician's assistant, and

Dr. Rainey assisting. According to Dr. Killmer's operative report, he initially encountered hemoperitoneum and aspirated several hundred milliliters. (Pl. Ex. 8, ECF 61-11.) He observed a moderate amount of clotted blood in Mrs. Runion's lower abdomen which he suctioned or scooped out by hand. Upon further exploration, he found a 15 centimeter segment of necrosis in the antimesenteric portion of the right colon with "free perforation." (*Id.*) Bowel contents spilled from the perforated bowel into Mrs. Runion's abdominal cavity. These were also suctioned and the perforation was controlled by a bowel clamp. Dr. Killmer's operative report further states: "The abdomen was copiously irrigated, and further exploration revealed the terminal small bowel to have multiple transverse segments of ischemic areas. These were felt to be secondary to distension, as opposed to thrombosis[.]" (*Id.*) Dr. Killmer ultimately removed the necrotic segment of the right colon as well as a 100 centimeter portion of the terminal ileum. He created an ileostomy and Mrs. Runion was taken to the recovery room in critical condition.

8. Mrs. Runion recovered from this second surgery well. Following the surgery, Mrs. Runion underwent an echocardiogram on September 12, 2008. It returned normal results with no evidence of intracardiac blood clots. (Def. Ex. 7, ECF 62-7.)

9. Mrs. Runion was transferred to Charleston Area Medical Center ("CAMC") at her husband's request on September 12, 2008. Dr. Justin Cohen, a CAMC hematologist and oncologist, was consulted about Mrs. Runion's tendency to develop blood clots in light of her history of MTHFR mutation. Dr. Cohen recommended that she be protected against the development of deep vein thrombosis during her recovery from her recent abdominal surgery with SCDs and Lovenox, an anti-coagulant medication. He wrote in his consultation summary, however, that "it is very unlikely that this [gene mutation] had an etiological role in [Mrs. Runion's] current situation." (Joint Ex. 2, ECF 65-3 at 15.) Mrs. Runion began to receive

Lovenox. Her physicians examined her lower legs by ultrasound on September 13, 2008, and did not find any evidence of deep vein thrombosis. (Def. Ex. 9, ECF 62-9.)

10. Mrs. Runion was discharged from CAMC on September 15, 2008. As noted on the discharge summary, her abdominal incisions were healing well. (Pl. Ex. 19(a), ECF 61-21.)

11. Mrs. Runion returned to CAMC on April 2, 2009 for an ileostomy reversal. The operation was normal and she was discharged home on April 7, 2009.

12. Since her September 10, 2008 abdominal surgery, Mrs. Runion has received ongoing care at CAMC's Surgery Clinic and Emergency Care Center, the Raleigh Boone Medical Center, and the Beckley Pain Clinic for Stomach and Back Pain for complaints of gastrointestinal pain, rectal bleeding, and chronic diarrhea.

III. PRELIMINARY CONCLUSIONS OF LAW

13. The FTCA renders the United States liable for the negligent acts of its employees committed "while acting within the scope of [their] employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b)(1). Access Health and Dr. Rainey are deemed to be employees of the United States under the Public Health Service Act and actions against them are treated as actions against the United States. 42 U.S.C. §§ 233(a), 254b. Because Plaintiffs allege that the purported negligence occurred in West Virginia, the Court is bound to apply West Virginia's substantive law, which, in cases such as this one involving medical negligence, is the MPLA. *See, e.g.*, *Osborne v. United States*, 166 F. Supp. 2d 479 (S.D. W. Va. 2001) (applying the MPLA); *Bellomy v. United States*, 888 F. Supp. 760 (S.D. W. Va. 1995) (same).

14. The MPLA sets forth the elements of a medical negligence claim as follows:

> (1) The health care provider failed to exercise that degree of care, skill and learning required or expected of a reasonable, prudent health care provider in the profession or class to which the health care provider belongs acting in the same or similar circumstances; and
>
> (2) Such failure was a proximate cause of the injury or death.

W. Va. Code § 55-7B-3(a)(1)-(2).

15. Thus, to prevail on a claim under the MPLA, the burden is on the plaintiff to prove, by a preponderance of the evidence, that the defendant was negligent and that the negligence was a proximate cause of the plaintiff's injury. *Sexton v. Greico*, 613 S.E.2d 81, 83 (W. Va. 2005) (per curiam) (quoting Syl. pt. 2, *Walton v. Given*, 215 S.E.2d 647 (W. Va. 1975)).

16. If the plaintiff proceeds on a "loss of chance" theory, he or she "must also prove, to a reasonable degree of medical probability, that following the accepted standard of care would have resulted in a greater than twenty-five percent chance that the patient would have had an improved recovery or would have survived." W. Va. Code § 55-7B-3(b).

17. A physician has a duty to render reasonable and ordinary care in the diagnosis and treatment of a patient. Syl. pt. 3, *Utter v. United Hosp. Ctr., Inc.*, 236 S.E.2d 213 (W. Va. 1977). A deviation from this duty is malpractice. *Kuhn v. Brownfield*, 12 S.E. 519, 521 (W. Va. 1890). In West Virginia, the standard of medical care is a national one. Syl. pt. 1, *Paintiff v. City of Parkersburg*, 345 S.E.2d 564 (W. Va. 1986). Whether a physician breached the applicable standard of care is to be judged at the time of his or her alleged negligent acts. *Bellomy*, 888 F. Supp. at 765 (citing Syl. pt. 2, *Shroeder v. Adkins*, 141 S.E.2d 352 (W. Va. 1965)).

18. A plaintiff is generally required to establish the applicable standard of care and breach thereof by use of expert testimony. W. Va. Code § 55-7B-7; *Bellomy*, 888 F. Supp. at 764. "Questions of an expert's credibility and the weight accorded to his testimony are ultimately for

the trier of fact to determine." *Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1183 (8th Cir. 1997). The court is not required to accept as true, and may afford proper weight to, expert testimony that is internally inconsistent or contradictory. *Holm v. United States*, 325 F.2d 44, 46 (9th Cir. 1963); *Jones v. Heckler*, 614 F. Supp. 277, 280 (D. Vt. 1985) (disregarding medical expert's testimony as not probative of plaintiff's medical condition because testimony was internally inconsistent and contradicted by other medical evidence of record).

IV. FINDINGS OF FACT AS TO EXPERT TESTIMONY

A. Plaintiffs' Expert Testimony

19. Plaintiffs presented expert testimony from three physicians: Dr. John A. Hayes, a board certified pathologist; Dr. Robert A. Dein, a board certified obstetrician and gynecologist; and Dr. Todd C. Campbell, a board certified surgeon.

1. Dr. Hayes

20. Dr. Hayes is an emeritus professor of pathology at the Boston University School of Medicine. (Pl. Ex. 25, ECF 61-6.) He practiced pathology from the time he graduated from medical school in 1956 through November of 2012, predominantly in the area of surgical diagnosis.

21. Dr. Hayes had been asked to study 25 pathology slides of Mrs. Runion's excised intestinal tissue to determine whether they revealed evidence of thrombotic activity. These slides were obtained from Raleigh General Hospital and were labeled A through Z.[2] Dr. Hayes described a thrombus as a blood clot that forms within a blood vessel where the blood is flowing. He added that "Lines of Zahn," which are characteristic of a true thrombus, consist of alternating

[2] The pathology slides were created by now-deceased Dr. S. Gerald Koh, a pathologist formerly practicing at Raleigh General Hospital.

bands of platelets and red blood cells. Lines of Zahn have a linear appearance that can be seen with the naked eye when viewing a thrombus within a blood vessel.

22. Of all the slides Dr. Hayes reviewed, Slide B was by far most significant in supporting the existence of thrombi. In Slide B, Dr. Hayes observed four tiny blood vessels containing small platelet thrombi. One vessel, he testified, showed a thrombus with the presence of Lines of Zahn. All told, Dr. Hayes found small platelet thrombi within vessels in four slides and larger thrombi in vessels in three slides. Most of the slides he reviewed did not contain any thrombi.

23. Dr. Hayes testified that the necrosis and perforation of Mrs. Runion's bowel was caused by ischemia, meaning inadequate blood flow. He qualified this opinion by testifying that he did not know what caused the ischemia itself. His review of this case was limited to his examination of the pathology slides. He did not review any of Mrs. Runion's clinical records or diagnostic tests or any of the legal pleadings or depositions taken in this case.

2. Dr. Dein

24. Dr. Dein's testimony centered on two main points. First, he testified that Dr. Rainey failed to meet the applicable standard of care in his treatment of Mrs. Runion. Second, he opined that Dr. Rainey's deviations from the standard of care caused Ms. Runion's bowel to perforate and necrotize. He held both opinions to a reasonable degree of medical probability.

25. Dr. Dein identified seven risk factors that he believed placed Mrs. Runion at an elevated risk of developing thrombosis. First, she had a prior stillbirth. Dr. Dein testified that this was significant because a stillbirth is often caused by poor blood flow through the placenta. Second, her prior stillbirth was thought to have been caused by placental abruption. Third, Mrs. Runion's infants were all small for gestational age. Dr. Dein testified the size of the fetus is indicative of placental health and nutrition, which could be linked to abnormal blood flow. Fourth, Mrs.

Runion had a long history of cigarette smoking and continued to smoke throughout her pregnancy. Dr. Dein explained that tobacco use interferes with the health of blood vessels and can cause disease within the blood vessels. Fifth, Mrs. Runion's amniotic fluid was low, possibly as a result of poor blood flow through the placenta. Sixth, Mrs. Runion carried an MTHFR gene mutation. Dr. Dein testified that certain varieties of this mutation have been associated with an elevated risk of clotting. Seventh, her Protein S levels were low. Patients with low Protein S levels, Dr. Dein testified, are more likely to develop abnormal clotting. While Mrs. Runion's Protein S was a level 55, Dr. Dein testified that the normal range is between 60 and 145.

26. Dr. Dein testified that in light of these risk factors, the standard of care required Dr. Rainey to place SCDs on Mrs. Runion's legs prior to her Cesarean section and to treat her with anti-coagulant medications immediately following the surgery. Dr. Dein believed that Mrs. Runion's infarcted bowel was caused by thrombosis.[3] He testified that if Dr. Rainey had taken these preventative measures, Mrs. Runion's abnormal clotting more likely than not would not have happened.

27. In support of his opinion that Dr. Rainey deviated from the standard of care, Dr. Dein relied on an August 2007 practice bulletin from the American Congress of Obstetricians and Gynecologists ("ACOG") entitled "Prevention of Deep Vein Thrombosis and Pulmonary Embolism." The bulletin addresses the prevention of deep vein thrombosis and pulmonary embolism following gynecological surgery. It recommends placement of SCDs and administration of low molecular weight heparin as prophylaxis for certain gynecology patients deemed at risk of developing deep vein thrombosis or pulmonary embolism. Dr. Dein testified

[3] Dr. Dein testified that though SCDs are used primarily to reduce the risk of deep vein thrombosis and pulmonary embolism, they improve circulation throughout the body and would have prevented the formation of thrombi within the intestines.

that although the bulletin addresses issues arising in gynecological surgery, its recommendations apply to Cesarean sections as well.

Dr. Dein was asked on cross-examination about a 2011 ACOG bulletin entitled "New Recommendations to Prevent Blood Clots During Cesarean Deliveries." This bulletin specifically indicates that women undergoing Cesarean sections should receive SCDs prior to their surgery. It also recommends that women with a medical or family history of thrombosis, or women that are considered high-risk for the development of thrombosis, should receive preventative treatment with anti-coagulant medication. Dr. Dein explained that the 2011 recommendations did not establish a new standard of care. In his opinion, they only reiterated the standard of care that existed at the time of Ms. Runion's September 4, 2008 Cesarean section.

28. Dr. Dein testified that Mrs. Runion's clinical course was not consistent with distension as the cause of her ischemic bowel. He concluded that a thrombotic event was the more likely explanation. He supported this conclusion by relying on the sudden, dramatic change in Mrs. Runion's vital signs after her Cesarean section and the lack of evidence of prolonged, massive over-distension of the bowel prior to the September 10, 2008 exploratory surgery.

3. Dr. Campbell

29. At the time of trial, Dr. Campbell was employed as an independent contractor practicing wound care. He testified that he had performed abdominal surgeries while in clinical practice as a general surgeon from 2003 until 2009.

30. Dr. Campbell testified that the ischemia and necrosis of Mrs. Runion's bowel was most likely caused by thrombosis. He did not agree with Dr. Killmer's operative finding that the necrosis was secondary to distention. Dr. Campbell reasoned that distension is not a diagnosis itself; rather, distension is always secondary to another abnormal process.

31. Dr. Campbell also testified, to a reasonable degree of medical probability, that Mrs. Runion suffers from "short gut" syndrome. Dr. Campbell was shown the parties' Joint Stipulation of Impairment, which lists Mrs. Runion's ongoing symptoms as chronic abdominal pain, stomach bloating, chronic diarrhea, chronic hemorrhoids, fatigue, malnutrition, and weight loss. (Joint Ex. 3, ECF 61-3.) These symptoms, Dr. Campbell testified, were all consistent with short gut syndrome.

B. Defendant's Expert Testimony

32. Mrs. Runion's treating physicians Dr. Rainey, Dr. Killmer, and Dr. Cohen all testified at trial as both fact witnesses and experts in their respective fields. The United States also offered expert testimony from Dr. Kris L. Sperry, a pathologist board certified in the fields of forensic, anatomic, and clinical pathology; and Dr. Larry P. Griffin, a board certified obstetrician and gynecologist.

1. Dr. Rainey

33. Dr. Rainey confirmed that he did not place SCDs on Ms. Runion's legs prior to her Cesarean section and did not order the administration of anti-coagulant medication, either pre- or post-operatively. He explained that it was not the standard of care at the time to use this prophylaxis for a patient who had no history of deep vein thrombosis or pulmonary embolism. He disagreed with Dr. Dein that the guidance set forth in the 2007 ACOG bulletin was meant to be applied to obstetric patients undergoing Cesarean sections.

2. Dr. Cohen

34. Dr. Cohen testified that approximately one-third of his clinical practice is devoted to treating patients with blood diseases and clotting disorders. He personally consulted with Mrs. Runion on September 12, 2008 to evaluate the significance of her MTHFR mutation, if any, to

her bowel problem. At trial, he summarized the applicable medical literature and testified that this MTHFR gene variant is no longer associated, as it once was, with an increased tendency to clot. He testified that recent research so thoroughly dispels this former theory that the current standard of care does not require physicians to test for the mutation. This research informed his conclusion that Mrs. Runion's MTHFR gene mutation was unrelated to her ischemic bowel.

3. Dr. Killmer

35. Dr. Killmer has been board-certified in the field of general surgery since 1998. He reaffirmed his operative finding that Mrs. Runion's ischemic bowel was due to distension as opposed to thrombosis. He relayed two primary reasons for this conclusion. First, the necrosis he observed was located in the antimesenteric portion of the bowel, or the area most distal from the arteries supplying blood to the intestines. Second, the necrosis appeared in a sporadic rather than a vascular pattern. If thrombosis had been the cause of the ischemia, he would expect to find necrosis throughout the small intestine rather than in random or isolated portions.

4. Dr. Sperry

36. As a forensic pathologist, Dr. Sperry's field of specialty deals specifically with causation. Dr. Sperry testified that the vast majority of cases he reviews concern allegations of medical negligence and that review of pathology slides is part of his daily practice. He estimated that he has examined large and small intestines in as many as 25,000 to 30,000 autopsies and that he has examined slides of intestines more than 20,000 times throughout his career. Of those slides, he estimated that between 8,000 to 10,000 showed evidence of blood clots or thrombosis.

37. Dr. Sperry described a thrombus as a specifically structured blood clot that forms within flowing blood. He compared the appearance of a thrombus to a brick wall, with red blood cells laid down in layers upon platelets. This layered pattern, he explained, is the hallmark of a

thrombus and allows a pathologist to distinguish between blood that has merely clotted or separated and a thrombus. The medical term for these "brick layers" is Lines of Zahn. Dr. Sperry explained that blood naturally separates whenever the heart ceases to pump or the blood vessels are clamped so that the blood is no longer flowing, but that this separation is not representative of a thrombus.

38. Dr. Sperry testified that he reviewed Mrs. Runion's pathology slides and medical records, the reports of Plaintiffs' expert witnesses, and the depositions of Dr. Cohen and Dr. Killmer in order to develop an opinion as to the cause of the ischemia. Like Dr. Hayes, Dr. Sperry focused his discussion of the pathology slides on Slide B. In Slide B, Dr. Sperry testified that he found a blood clot in a vessel that was, when unmagnified, smaller than a period at the end of a sentence. He explained that the blood had stopped flowing inside this vessel as a result of the surgical clamping and had thus separated into platelets and red blood cells. He testified that this separation was not Lines of Zahn that had formed while blood was still flowing within the vessel. He concluded that this clot was not a thrombus, but merely blood that had pooled and clotted when the necrotic bowel was removed. After his review of all of the pathology slides, Dr. Sperry found no evidence of thrombosis. Mrs. Runion's vessels were either empty or contained clumps of blood that clotted after Dr. Killmer surgically cut off the blood flow and removed the tissue.

39. Dr. Sperry testified to a reasonable degree of medical probability that Mrs. Runion's infarcted bowel was caused by a paralytic ileus that developed after her Cesarean section. This ileus caused her bowel to swell and enlarge. Eventually this swelling, or hyper-distension, built pressure from inside of the bowel outward to a degree that it cut off the blood flow in the bowel wall and brought about the resulting necrosis.

40. Dr. Sperry also testified to a reasonable degree of medical probability that Mrs. Runion's bowel problem was not caused by thrombosis or any abnormal thrombotic process. In his report prepared in anticipation of trial, Dr. Sperry outlined six pathologic elements that eliminated this possibility.

> First, extensive tissue sectioning was performed by Dr. Koh, and if the ischemic necrosis was on the basis of abnormal thrombosis, then there should be innumerable significant thrombi present throughout essentially every tissue section. Instead, there were no definitive thrombi, and the occasional evidence of clotting is primarily within capillaries and very small venules, without distension or endothelial adherence.
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> Second, the antimesenteric location of the areas of ischemia noted by the surgeon are distinctly unusual; thrombotic-induced ischemia typically involves the arterioles and venules on the mesenteric side, where the mesenteric vascular arcades feed in to and drain the bowel.
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> Third, the surgeons did not find any evidence of any thrombosis within the mesenteric vasculature, or at any other location.
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> Fourth, the ischemia was completely isolated to the right colon, cecum and distal ileum, and nowhere else, which would have been the appearance and pathologic manifestations of abnormal hypercoagulation-induced thrombosis.
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> Fifth, Mrs. Runion's bowel healed uneventfully after the definitive surgical bowel resection, even with the evidence of ischemic damage at the small bowel margin. If abnormal thrombosis had been the etiology of the ischemic damage, residual thrombi would have remained at the resection margins and elsewhere in the bowel, producing inadequate healing, and probable further ischemic necrosis. This did not occur.
>
> Sixth, if the etiology of the ischemic necrosis had been thrombotic in nature, then neither surgical resection nor institution of anticoagulation would have changed, altered, nor eliminated any thrombi. The administration of anticoagulation medications will inhibit the formation of new thrombi, and limit the extension of existing thrombi, but have no effect on thrombi that already exist. Thus, if abnormal thrombosis had been the cause of her ischemic bowel necrosis, there is nothing that would have prevented further extension of the necrosis despite the surgical intervention. As stated above, this did not happen; she recovered, with no further evidence of bowel necrosis, or involvement of any other organ.

(Def. Ex. 2, ECF 62-2 at 3.) Dr. Sperry opined that if there had been thrombi in Mrs. Runion's bowel, the thrombotic process would not have been cured by removal of the necrotic portions. The thrombotic disease would have continued and likely necessitated further surgeries.

41. Dr. Sperry also opined to a reasonable degree of medical probability that the few blood clots that he did observe in the pathology slides in no way contributed to Mrs. Runion's ischemic bowel. He explained that these clots developed during the surgical process of removing the bowel. Once the bowel was clamped, the blood in that portion of the intestine ceased flowing and started to clot. The blood separated at that point because it was no longer being pumped by the heart. These clots, in his opinion, were caused by surgical interruption of the bowel's blood flow and by nothing else.

5. Dr. Griffin

42. Dr. Griffin testified to a reasonable degree of medical probability that Dr. Rainey's treatment of Mrs. Runion met the standard of care. In his opinion, the standard of care in 2008 for a patient with Mrs. Runion's background undergoing a Cesarean section did not require the placement of SCDs or the administration of an anti-coagulant medication such as Lovenox.

43. He testified that Mrs. Runion had only two risk factors bearing on her propensity to develop thrombosis. These were her pregnancy itself and her history of smoking. He disagreed with Dr. Dein that Mrs. Runion's MTHFR gene mutation and Protein S levels elevated her risk of clotting. Though her lab work revealed that she carried an MTHFR gene mutation, Dr. Griffin testified that Mrs. Runion did not have the type of gene mutation related to an increased likelihood of clotting. Mrs. Runion's Protein S level was a 55. For non-pregnant women, a level below 60 is abnormal. Dr. Griffin testified that Protein S levels decrease in a normal pregnancy, however, and that the ACOG suggests that normal Protein S values in a pregnant woman may

drop to 24 to 30. He disagreed that Ms. Runion's prior stillbirth and prior placental abruption were related to a clotting disorder because he believed placental abruption to be primarily related to hypertension, smoking, or general atherosclerosis.

44. Dr. Griffin testified that in 2008, there were no guidelines recommending the use of anti-coagulant medications or SCDs before or after a routine Cesarean section. He testified that the ACOG Guidelines changed in 2011 when the ACOG recommended routine use of SCDs with patients undergoing surgery for Cesarean section. Administration of anti-coagulants such as Lovenox, however, still is not recommended as the routine standard of care in Cesarean patients. He testified that administration of anti-coagulants to a patient receiving spinal anesthesia, such as Mrs. Runion, puts the patient at risk of bleeding into the spinal column. Further, he opined that because Mrs. Runion experienced significant post-operative bleeding, administration of an anti-coagulant shortly after her Cesarean section would have dangerously increased her bleeding.

45. Dr. Griffin did not agree with Dr. Dein that Mrs. Runion's ischemic bowel was the result of a failure to guard her against clotting. Instead, he testified to a reasonable degree of medical probability that Mrs. Runion's condition was caused by Ogilvie's syndrome. He explained that this term is used to describe a scenario where massive distension from inside the small intestine and colon puts increased pressure on the blood vessels along the wall of the intestine, ultimately resulting in death and perforation of the intestinal wall. Dr. Griffin testified that Ogilvie's syndrome is often diagnosed as bowel distension. He also testified that since her condition was unrelated to thrombosis, treating Mrs. Runion with anti-coagulants or SCDs would not have prevented this syndrome from occurring.

V. FINDINGS OF FACT WITH REGARD TO LIABILITY

A. Standard of Care

46. Plaintiffs allege that in light of Mrs. Runion's high risk for developing thrombosis, Dr. Rainey deviated from the standard of care by failing to treat her with SCDs and anti-coagulant medications.

47. Plaintiffs identified seven risk factors that potentially increased Mrs. Runion's risk of developing thrombosis. Based on Dr. Dein's testimony, these included (1) Mrs. Runion's prior stillbirth, (2) her prior placental abruption,[4] (3) her small for gestational age babies, (4) her history of cigarette smoking and tobacco use throughout pregnancy, (5) her low amniotic fluid, (6) her MTHFR gene mutation, and (7) her low Protein S levels. All other expert and treating physician testimony confirmed that Mrs. Runion's continued cigarette smoking increased her clotting risk, as did her pregnancy itself. The significance of Dr. Dein's other risk factors was the subject of much dispute.

48. The difficulty in parsing out the significance of Dr. Dein's risk factors lies partly in the disproportionate impact of Mrs. Runion's history of cigarette smoking on her clinical history. Dr. Griffin viewed several of Dr. Dein's risk factors, including the prior stillbirth with placental abruption and small for gestational age babies, as stemming from cigarette smoking rather than as being independently associated with vascular problems. The Court is inclined to agree since Mrs. Runion's diagnostic tests did not identify her as high risk for developing thrombosis. With the exception of her MTHFR gene mutation, the significance of which was persuasively dispelled by Dr. Cohen's testimony, Mrs. Runion's thrombophilia workup early in her pregnancy returned normal results. The Court is also persuaded by Dr. Griffin's testimony that Mrs. Runion's Protein S level was normal for a pregnant woman and, accordingly, had no bearing on her tendency to clot. Mrs. Runion has no personal or family history of deep vein thrombosis or

[4] Dr. Dein's first and second risk factors are one in the same. Mrs. Runion's prior stillbirth was thought to have been caused by placental abruption.

pulmonary embolism and numerous tests performed after her Cesarean section never revealed any evidence of either disease.

49. Plaintiffs have insisted that Dr. Griffin's assessment of Mrs. Runion's clotting risk is not credible because it contradicts other expert opinion in this case. They rely in particular on the testimony of Dr. Killmer. Dr. Killmer's testimony was not as favorable to Plaintiffs as they have indicated and certainly did not contradict Dr. Griffin's well-founded opinion. Dr. Killmer was asked on cross-examination if low Protein S levels were "maybe" a risk factor in developing thrombosis, to which he replied that they were. Plaintiffs' counsel did not ask what level would be considered low for a pregnant woman, and Dr. Killmer did not opine whether Protein S levels normally drop during pregnancy. Dr. Killmer also testified that a patient's prior stillbirth would "possibly" give him concern over a clotting disorder. The Court places little weight on these lukewarm responses. It therefore **FINDS** that Plaintiffs have not proven, by a preponderance of the evidence, that Mrs. Runion was high risk for developing thrombosis.

50. After consideration of the contradictory evidence regarding Mrs. Runion's risk factors, the Court **FINDS** that the standard of care at the time of Mrs. Runion's September 4, 2008 Cesarean section did not require Dr. Rainey to place SCDs or to administer anti-coagulant medication. Both parties' obstetric experts agreed that the current standard of care requires the placement of SCDs before routine Cesarean surgeries. The question before the Court is whether the standard of care in 2008 required that Mrs. Runion be treated with SCDs and anti-coagulants. Dr. Dein testified that it did.[5] He supported his opinion by relying on the 2007 ACOG practice

[5] The United States sought to impeach the credibility of Dr. Dein's testimony on this point by referencing a Food and Drug Administration ("FDA") black box warning for Lovenox, a type of low-molecular weight heparin. This black box warning apparently cautions against the administration of Lovenox to patients receiving spinal anesthesia. Plaintiffs objected to this line of questioning because the FDA black box warning had not been disclosed in discovery. The United States responded that the Federal Rules of Civil Procedure do not require disclosure of material that will be

bulletin which, he admitted, addresses preventative care in gynecological surgeries, not Cesarean sections. He had no other medical literature predating Mrs. Runion's Cesarean section to support his opinion on the standard of care.

Dr. Dein's opinion about the standard of care was significantly undermined by Dr. Griffin's testimony. Dr. Griffin testified that the recommendations set forth in the 2011 ACOG practice bulletin entitled "New Recommendations to Prevent Blood Clots During Cesarean Deliveries" led to a change in obstetric practice. Prior to 2011, Dr. Griffin testified that the evidence supporting the use of SCDs was tenuous and the devices were not used as a matter of course. With the issuance of the new recommendations, however, obstetricians were encouraged to begin to place SCDs in routine Cesarean sections. Unlike in 2008, he testified that the standard of care now requires a physician to seriously consider using these devices. While the benefit of SCDs is still subject to dispute, Dr. Griffin opined that the low cost and low risk associated with placing the SCDs now advocates in favor of their use. Dr. Dein's position that the 2011 recommendations did not reflect a change in the standard of care thus seems illogical. The testimony in this case has without question established the authority of the ACOG practice bulletins among obstetricians. By characterizing these 2011 recommendations as new, the ACOG must have intended them to represent a change from previous practice.

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used exclusively to impeach another party's witness. *See* Fed. R. Civ. P. 26(a)(3)(A). The Court took the objection under advisement. The Court now **OVERRULES** the objection and **FINDS** that the FDA black box warning was not subject to pretrial disclosure because it was used solely for impeachment purposes. The Court does not find the black box warning particularly illustrative of the standard of care, however, because Dr. Dein explained that the black box warning refers only to the administration of Lovenox prior to spinal anesthesia. In his opinion, Mrs. Runion should have received anti-coagulants *after* her Cesarean section. Dr. Rainey testified that after the 2011 ACOG bulletin was issued, he and his partners began routine administration of Lovenox themselves—despite the FDA's black box warning. Dr. Rainey testified that the Lovenox is typically administered the morning after a Cesarean section, and that by this time the risk of bleeding into the spine has substantially decreased. Since the United States' attempt to impeach Dr. Dein on this point was undermined by the testimony of its own witness, the Court does not consider the black box warning relevant in determining the standard of care.

Dr. Dein's testimony regarding the administration of anti-coagulant medications following a Cesarean section was similarly unconvincing. It seems clear that the 2007 practice bulletin recommending the administration of anti-coagulants to high-risk patients following gynecological surgeries cannot necessarily be applied to Cesarean sections. As Dr. Griffin testified, differences in blood volume, blood flow, cardiac output, and coagulation factors between pregnant and non-pregnant women require obstetricians to use greater caution when administering anti-coagulants to women who are pregnant or who have recently undergone a Cesarean section. The risks associated with administering anti-coagulants to a patient receiving spinal anesthesia also persuade the Court that the guidelines applicable to gynecological surgeries cannot transfer to Cesarean sections as readily as Dr. Dein suggested.

51. The Court finds Dr. Griffin's testimony, corroborated by the new guidelines issued by ACOG in 2011 and Mrs. Runion's medical history showing extensive post-operative bleeding, to be more credible than Dr. Dein's. The Court therefore **FINDS** that the standard of care at the time of Mrs. Runion's September 4, 2008 Cesarean section did not require preventative treatment with SCDs and anti-coagulant medications.

B. Causation

52. Even assuming that Plaintiffs have proven that Dr. Rainey's treatment of Mrs. Runion deviated from the standard of care, they have not proven by a preponderance of the evidence that these deviations were a proximate cause of Mrs. Runion's ischemic bowel.

53. Plaintiffs theorize that Mrs. Runion's bowel problem was caused by thrombosis, a condition preventable by the placement of SCDs and the administration of anti-coagulants. Plaintiffs' theory of causation compelled them to discredit Dr. Killmer's operative findings, which concluded that the ischemia was secondary to distension rather than thrombosis. They

attempted to do so through the expert testimony of Dr. Hayes, Dr. Dein, and Dr. Campbell.[6] Though Dr. Dein and Dr. Campbell testified that Mrs. Runion's bowel problem was most likely caused by a thrombotic event, these opinions are not supported by the weight of the evidence. To use Dr. Sperry's words, the tissue sectioning performed by the Raleigh General Hospital pathologist was "extensive." (Def. Ex. 2, ECF 62-2 at 3.) Plaintiffs' own pathology expert, however, located only a handful of microscopic thrombi within the pathology slides. Most of her blood vessels were clear. Dr. Hayes was also not able to link these thrombi to the cause of the ischemia. He did not review any of Mrs. Runion's clinical records or diagnostic tests and admitted that he did not know what caused the thrombi to form. The Court can give little credence to the opinions of Dr. Dein and Dr. Campbell when Plaintiffs' own pathologist was unwilling to draw these same conclusions.

The reliability of Dr. Dein and Dr. Campbell's opinions is suspect for other reasons. Dr. Dein previously testified as an expert witness in *Holli Davis v. United States*, Civil Action No. 5:10-cv-00384, a case tried in this district before Judge Irene C. Berger. In that case, Dr. Dein testified that pathology is just one factor to be considered in determining a patient's diagnosis. Judge Berger found that this testimony contradicted Dr. Dein's prior testimony in a Mingo County, West Virginia circuit court case styled *Candace Norman v. Health Management Associates*, Civil Action No. 97-C-308. In that case, Dr. Dein had testified that "the major proof is the operative findings" and that "the pathology report . . . really proves your diagnosis." *Davis*, 2012 WL 2681426, *10 (S.D. W. Va. July 6, 2012). Dr. Dein's attempts to downplay the significance of Dr. Killmer's operative report are discredited by this prior testimony.

[6] Plaintiffs also insinuate that Dr. Rainey influenced Dr. Killmer's conclusions by being present in the operating room. Dr. Rainey testified that he and Dr. Killmer had a friendly relationship that at times extended to recreational events outside the hospital. Dr. Killmer denied that Dr. Rainey's presence influenced his surgical findings in any way. Because the United States' evidence conclusively rules out the existence of thrombosis, Plaintiffs' suggestion of bias is unpersuasive.

The strength of Dr. Campbell's opinions was overshadowed by his inexperience. Dr. Campbell began clinical practice in just 2003 and, while he initially practiced general surgery, he was employed at the time of trial as an independent contractor specializing in wound care. Dr. Campbell repeatedly testified that the average adult has two feet of small intestine, a point which, to his credit, he retracted when questioned directly by the Court. His opinion as to causation was rendered in a conclusory manner. He summarily rejected Dr. Killmer's operative findings because he reasoned that distension is secondary to something else. Without more, this testimony is insufficient to undermine Dr. Killmer's operative report.

54. Unlike any of Plaintiffs' expert witnesses, Dr. Sperry examined both the pathology slides and Ms. Runion's medical records before rendering an opinion as to causation. Dr. Sperry was thus able to synthesize the competing evidence in a manner unparalleled by Dr. Hayes, Dr. Dein, or Dr. Campbell. Dr. Sperry testified that he observed several blood clots in the pathology slides, but that these were not true thrombi. His familiarity with the operative report influenced his opinion that this blood had merely separated after Mrs. Runion's bowel was clamped during her surgical procedure. The operative report also noted the antimesenteric location of the areas of ischemia. Dr. Sperry reasoned that this unusual location did not comport with a theory of thrombosis as the etiology. Dr. Hayes, on the other hand, evaluated Mrs. Runion's tissue samples in a vacuum. He did not recall whether he had even read Dr. Killmer's operative report. Because Dr. Sperry's opinion was based on an assessment of Mrs. Runion's entire clinical course and not just the pathology slides, the Court finds his testimony far more credible.

55. Mrs. Runion's clinical outcome makes the likelihood of thrombosis even more remote. Dr. Sperry testified that if Mrs. Runion had developed thrombi within the bowel, the problem would not have been cured by removal of the necrotic portions. Residual thrombi would have

been scattered throughout her bowel and subsequent surgeries likely would have been needed. Dr. Sperry also testified that starting anti-coagulant medications after the abdominal surgery would not have altered this outcome. Anti-coagulants prevent the formation of new thrombi and prevent existing thrombi from spreading, but they have no effect on thrombi that already exist. Mrs. Runion's ischemia was cured by the removal of the necrotic bowel observed by Dr. Killmer during her September 10, 2008 surgery. She did not suffer any further necrosis and required no subsequent surgery. For all these reasons, the Court is convinced by Dr. Sperry's conclusion that no thrombosis existed. Mrs. Runion's ischemic bowel was more likely the result of "non-thrombotic vascular stasis" brought about by the development of a post-Cesarean ileus. (Def. Ex. 2, ECF 62-2 at 3.) The term "ileus" describes the non-mechanical obstruction, or blockage, of the bowel. This ileus led to massive distension which, in turn, drastically increased the pressure inside the bowel and interrupted the blood flow within the intestinal wall.

56. Dr. Griffin confirmed Dr. Sperry's reasoning. He opined that it is relatively common for a patient recovering from a Cesarean section to develop an ileus, particularly when the patient is a cigarette smoker and has been given spinal anesthesia as Mrs. Runion was. His characterization of Mrs. Runion's condition as Ogilvie's syndrome only put a name to what Dr. Sperry had previously described. Based on the testimony of Dr. Sperry and Dr. Griffin and on Dr. Killmer's operative report, the Court **FINDS** that the necrosis and perforation of Mrs. Runion's bowel was not caused by thrombosis.

57. Because Mrs. Runion did not develop thrombosis, the Court also finds that her condition was not preventable by the placement of SCDs and the administration of anti-coagulant medications. Dr. Griffin testified that these measures would have had no effect on Mrs. Runion's bowel problem. He testified that SCDs and anti-coagulants are meant to prevent the

propagation of thrombi in the deep veins of the calf or the pelvis. Plaintiffs concede that Mrs. Runion never developed deep vein thrombosis or pulmonary embolism. Dr. Griffin also testified that Mrs. Runion suffered from significant post-Cesarean bleeding and that administering anti-coagulant medications to her soon after her surgery would have only exacerbated her condition. This opinion is consistent with that of Dr. Haddadin, one of Mrs. Runion's consulting physicians at Raleigh General Hospital. After her consultation of September 8, 2008, Dr. Haddadin recommended against anti-coagulants due to Mrs. Runion's anemia and gastrointestinal bleeding. (Pl. Ex. 13, ECF 61-15 at 4.) The Court therefore **FINDS** that Plaintiffs have not proven by a preponderance of the evidence that their suggested prophylaxis would have altered Mrs. Runion's clinical outcome.

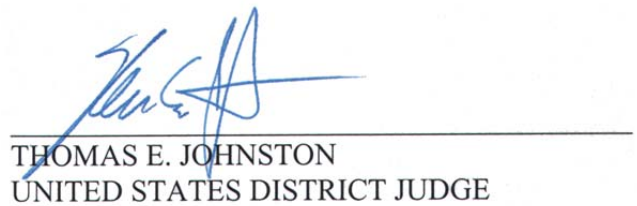
VI. FINAL CONCLUSIONS OF LAW

58. The Court concludes that Plaintiffs have failed to prove the requisite elements of an MPLA cause of action by a preponderance of the evidence. The Court therefore **FINDS** that Defendant is not liable to Plaintiffs for medical negligence. Judgment will be entered in favor of Defendant and this case will be removed from the Court's docket.

IT IS SO ORDERED.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 12, 2013



THOMAS E. JOHNSTON
UNITED STATES DISTRICT JUDGE